

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
FILING COMPLETION UNDER 37 CFR 52, 53, and/or 85

In re Application of: Simionescu, et al.

Serial No: 10/722,581

Filed: November 24, 2003

Confirmation No: 5668

Title: Tissue Method And Process For Bioprosthesis

Commissioner for Patents

U.S. Patent and Trademark Office

Post Office Box 1450

Alexandria, VA 22313-1450

Sir:

The following completes the filing of the above-identified patent application under Rule 52, 53, and/or 85:

- ☒ Rule 53 signed Declaration enclosed.
☐ This is a Rule 47 filing per attached Petition.
☐ Enclosed: Original signed Declaration with attached specification (including claims) which is a copy of specification/claims originally filed to secure above filing date.
☐ Specification originally filed in non-English language; hence verified translation attached of:
☐ Abstract ☐ pages of Specification (only spec. & claims) ☐ Drawing Figs.
☐ sheet(s) of formal drawings enclosed: size: ☐ A4 ☐ 14" ☒ 8 1/2 by 11
☒ Attached is an assignment to Clemson University.
☐ Priority is hereby claimed under rule 55 and 35 U.S.C. 119 based on prior foreign application(s) no(s).
_____, filed in _____ on _____, respectively.
Certified copy (copies) ☐ attached; ☐ already filed on _____ in U.S. Application, Serial No. _____, filed _____.
☒ "Small Entity" status under Rule 27 claimed. ☐ Attached: _____ Verified Statement(s) establishing "small entity."
☒ Attached is the request return copy of the PTO Notice under Rule 52, 53, and/or 85.
☒ Attached: Information Disclosure Statement and Related Applications Form
☐ Preliminary Amendment: _____

THE FOLLOWING FILING FEE IS BASED ON CLAIMS AS FILED LESS ANY ABOVE CANCELLED
PER MPEP § 506 AND § 607

If not earlier paid, add Basic Filing Fee	\$ 770.00
Total Effective Claims <u>33</u> - 20 = <u>13</u> x \$18.00 =	\$ 234.00
Independent Claims <u>4</u> - 3 = <u>1</u> x \$86.00 =	\$ 86.00
If <u>any proper</u> multiple dependent claim (ignore improper) is present, add \$290.00	\$.00
Filing Fee	\$.00

Since PTO Notice under Rule 52, 53, and/or 85 set an original due date of May 2, 2004, petition is hereby made for an extension to cover the date this response is filed for which the requisite fee is enclosed (1 month \$110; 2 months \$420; 3 months \$950; 4 months \$1480).

\$.00

If this is the first time either signed Declaration filed or filing fee paid, add Surcharge (\$130)

\$ 130.00

Subtotal

\$ 1,220.00

If "small entity" status box above is X'd, enter half (1/2) of subtotal & subtract

\$ 610.00

Total

\$ 610.00

If "non-English" box above is X'd, add Rule 17(i) or (k) processing fee \$130.00)

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If "assignment" box is X'd, add recording fee (\$40.00).

\$ 40.00

If "Rule 47" box above is X-d, add Petition fee \$130.00 Rule 17(h).

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TOTAL FEE ENCLOSED

\$ 650.00

The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any fees in addition to the fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (deficiency only) now or hereafter relative to this application and the resulting official document under Rule 20, or credit any overpayment, to our Account No. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached. This statement does not authorize charge of the issue fee in this case.

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By: Christina L. Mangelsen Reg. No. 50,244 Date: 04/19/2004

Signature: Christina L. Mangelsen


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Sandra S. Perkins

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(Signature of person mailing paper or fee)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Simionescu, et al.		Group Art Unit:	3738
Serial No:	10/722,581		Examiner:	Unknown
Filed:	November 24, 2003		Our Account No:	04-1403
Confirmation No:	5668		Customer No:	22827
Title:	Tissue Material and Process For Bioprosthesis			

Commissioner for Patents
U.S. Patent and Trademark Office
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Sir:

The following is an Information Disclosure Statement for the captioned patent application, pursuant to 37 CFR Sections 1.56, 1.97, and 1.98.

1.[x] Attached hereto is:

- a.[x] A list of materials for consideration per Rule 98(a)(1): 2 page(s)
- b.[x] A legible copy of each patent, publication, or other item listed per Rule 98(1)(2), unless not required per Rule 98 and/or as indicated on the attached list(s):
29 item(s)
- c.[] For each non-English language item listed, pursuant to Rule 98(a)(3), a concise explanation of the relevance thereof as it is presently understood by the individual designated in Rule 56(c) most knowledgeable about the content of such items: _____

[] Such explanation is provided in the Search Report from a corresponding application enclosed herewith along with any enclosed translation into English.

2.[x] This Information Disclosure Statement is being filed [CHECK ONE]:

- a.[x] WITHIN THREE MONTHS of the application filing date, national stage date of entry, or along with or after a request for continued examination, OR BEFORE the mailing date of a first Office Action on the merits, which ever event occurs last, WHEREFORE per Rule 97(b) NO filing fee or Rule 97(e) certificate is required.
- b.[] AFTER the time periods of section 2.a above, but BEFORE a Final Action, Notice of Allowance OR an action that otherwise closes prosecution, WHEREFORE PER Rule 97(c) submitted herewith is [CHECK ONE]:
 - i.[] Certification per Rule 97(e); OR
 - ii.[x] Filing Fee per Rule 17(p)\$180.00
- c.[] AFTER a Final Action OR Notice of Allowance, but BEFORE payment of the issue fee, WHEREFORE per Rule 97(d) submitted herewith is:
 - i. Certification per Rule 97(e); AND
 - ii. Filing fee per Rule 17(p)\$180.00

3.[] Rule 97(e) Certification; per Rule 97(e), the undersigned certifying party make the following certification statement [CHECK ONE]:

- a.[] That each item of information contained in this Information Disclosure Statement was first cited in a communication from a foreign patent office in a counterpart foreign application not more than three months prior to the filing of this statement; OR
- b.[] That no item of information contained in this Information Disclosure Statement was cited in a foreign patent office in a counterpart foreign application and to the knowledge of the undersigned after making a reasonable

inquiry, was known to any individual designated in Rule 56(c) more than three months prior to the filing of this statement.

CERTIFYING PARTY (if different from bottom signature; omission here indicates that certification is being made by signer per signature below).

Name: _____

Signature: _____

Address: _____

Date: _____

- 4.[x] DEPOSIT ACCOUNT AUTHORIZATION: The Commissioner is hereby authorized to charge any fee specifically authorized hereafter, or any fees in addition to the fee(s) filed, or asserted to be filed, or which should have been filed herewith or concerning any paper filed hereafter, and which may be required under Rules 16-18 (deficiency only) now or hereafter relative to this application and the resulting official document under Rule 20, or credit any overpayment, to our Account No. shown in the heading hereof for which purpose a duplicate copy of this sheet is attached. This statement does not authorize charge of the issue fee in this case.
- 5.[x] CERTIFICATE OF MAILING: This Information Disclosure Statement is being filed pursuant to [CHECK AND COMPLETE ONE]:

- a.[x] First Class Mail Certificate of Mailing under Rule 8:

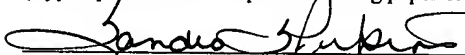
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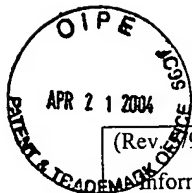
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By: Christina L. Mangelsen, Patent Agent

Reg. No: 50,244

Signature: 

Date: April 19, 2004



(Rev. 92) Information Disclosure Statement List By Applicant(s) Under 37 CFR Section 1.98(a) (1) (Use several sheets if necessary)	Attorney Docket Number: CXU-378	Serial Number: 10/722,581
	Applicant: Simionescu, et al.	
	Filing Date: November 24, 2003 Confirmation No: 5668	Group Art Unit: 3738

- NOTE: If no indication is made in the column marked "COPY NOTE," the required legible copy of the corresponding item is submitted herewith; otherwise, a copy is not required and/or not submitted, for the following reason(s) [corresponding reason number is listed in "COPY NOTE" column]
- (1) This item is cumulative, per Rule 98(c)
 - (2) A copy of this item was previously cited by or submitted to the U.S. Patent and Trademark Office in:
 USSN _____, filed _____, or
 USSN _____, filed _____;
 Relied on under 35 U.S.C. Section 120, per Rule 98(d)
 - (3) Both reasons (1) and (2) apply
 - (4) No legible complete copy is possessed, in custody of controlled, or readily available
 - (5) Per the U.S. Patent and Trademark Office's waiver of Rule 98(a)(2)(i), the item is a U.S. patent or patent application publication, and the present application was filed after June 30, 2003.

U.S. PATENT DOCUMENTS										
EXAMINER INITIALS	PATENTEE NAME	PATENT NUMBER							ISSUE DATE	COPY NOTE
	Huynh, et al.	6	1	0	2	9	4	4	08/15/2000	5
	Cosgrove, et al.	6	1	9	7	0	5	3	03/06/2001	5
	Carpentier, et al.	6	2	1	0	9	5	7	04/03/2001	5
	Cunanan, et al.	6	2	1	4	0	5	4	04/10/2001	5
	Nguyen, et al.	6	2	4	5	1	0	5	06/12/2001	5
	Shannon, et al.	6	2	6	7	8	3	4	07/31/2001	5
	McIntyre, et al.	6	2	7	8	0	7	9	08/21/200	5
	Carpentier	6	3	3	8	7	4	0	01/15/2002	5
	Nguyen-Thien-Nhon	6	3	4	2	0	7	0	01/29/2002	5
	Ekholm, Jr., et al.	6	3	7	8	2	2	1	04/30/2002	5
	Williamson, IV, et al.	6	4	0	2	7	8	0	06/11/2002	5
	Stobie, et al.	6	4	0	9	7	5	8	06/25/2002	5
	Nguyen, et al.	6	4	1	3	2	7	5	07/02/2002	5
	Erickson, et al.	6	4	1	6	5	4	7	07/09/2002	5
	Schreck	6	4	5	4	7	9	9	09/24/2002	5
	Van Nguyen, et al.	6	4	5	8	1	5	5	10/01/2002	5
	Cao	6	4	6	1	3	8	2	10/08/2002	5
	Rollero, et al.	6	5	0	6	1	9	7	01/14/2003	5
	Hill, et al.	6	5	3	2	3	8	8	03/11/2003	5
	Lam	6	5	3	9	9	8	4	04/01/2003	5
	Carpentier, et al.	6	5	4	7	8	2	7	04/15/2003	5
	Carpentier, et al.	6	5	5	8	4	1	8	05/06/2003	5
	Carpentier, et al.	6	5	6	1	9	7	0	05/13/2003	5
	Spievack	6	5	7	9	5	3	8	06/17/2003	5
	Huynh, et al.	6	5	8	5	7	6	6	07/01/2003	5
	Burnside, et al.	6	6	2	6	9	3	9	09/30/2003	5

U.S. PATENT APPLICATION PUBLICATIONS										
EXAMINER INITIALS	APPLICANT'S NAME	PUBLICATION NUMBER							PUBLICATION DATE	COPY NOTE
	Vesely, et al.	0	0	9	5	9	9	4	07/25/2002	5



(Rev. 5/92) Information Disclosure Statement List By Applicant(s) Under 37 CFR Section 1.98(a) (1) (Use several sheets if necessary)	Attorney Docket Number: CXU-378	Serial Number: 10/722,581
	Applicant: Simionescu, et al.	
	Filing Date: November 24, 2003 Confirmation No: 5668	Group Art Unit: 3738

FOREIGN PATENT DOCUMENTS									
EXAMINER INITIALS	COUNTRY	DOCUMENT NUMBER	PUBLICATION DATE	TRANSLATION			COPY NOTE		
				YES	NO	N/A			

*"NO" means that no copy of an English language translation is within the possession, custody, or control of, or is readily available to any individual designated in Rule 56(c).

EXAMINER INITIALS	OTHER DOCUMENTS Specify author (if any), Title, Pertinent Pages, Date & Place of Publication	COPY NOTE
	Article – <i>Aluminum Chloride Pretreatment of Elastin Inhibits Elastolysis by Matrix Metalloproteinases and Leads to Inhibition of Elastin-Oriented Calcification</i> , Michael Bailey, Hui Xiao, Matthew Ogle, and Naren Vyavahare, The American Journal of Pathology, Vol. 159, 2001, pp. 1981-1986	ajp.amjpathol.org, 11/17/2003
	Paper from Cedars-Sinai Medical Center entitled "Cedars-Sinai Medical Center Prosthetic Heart Valve Information", 37 pages	
EXAMINER	DATE CONSIDERED	
Examiner: initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include a copy of this form with the next communication to applicant.		